JAN 1 8 2001

K003454

A1-CS-SB Y-Adapter
Additional Information for Special 510(k) #K003454

1. 510(K) SUMMARY

Name and Address of Sponsor:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name:

Proprietary Name	A1-CS-SB Y-Adapter
Classification	Class III (21 CFR 870.3620)
Classification Name	Pacemaker Lead Adapter
Product Code	DTD

General Description and Predicate Devices:

BIOTRONIK's A1-CS-SB Y-Adapter is intended to bifurcate one bipolar pacing and sensing channel (IS-1) of a pulse generator to allow two unipolar leads (or bipolar functioning as unipolar) to be connected to both the cathode and anode of the pulse generator's channel. The A1-CS-SB Y-Adapter is substantially equivalent to BIOTRONIK's A1 Series of Adapters (#K970388, cleared 08-14-97) as the proximal end of the A1-CS-SB Y-Adapter is identical in design, materials and functionally equivalent to the proximal end of the A1 Adapters already cleared for distribution. The distal connector, that bifurcates the pacing and sensing channel, consists of two IS-1 unipolar connector ports that are contained within a header. The header is comprised of the same materials (epoxy resin and hardener) contained in the headers of BIOTRONIK's market-releaed pulse generators such as the Pikos family of pulse generators (#K945627, cleared 03-05-96). Additionally, in the same manner as BIOTRONIK's pulse generator headers are designed to be self-sealing, the A1-CS-SB Y-Adapter is self-sealing and includes setscrews that are accessed through self-sealing silicone plugs.

Indications for Use:

Lead adapters, including silicone adapter sleeves, when used in conjunction with their accessories, provide a means of securely connecting pace/sense leads with otherwise mechanically incompatible pacemaker devices.

Name and Address of Manufacturing Site:

BIOTRONIK GmbH & Co.
Woermannkehre 1, Berlin, Germany
011-49-30-689-05-304

Manufacturer Registration No.: 9610139

Contact Person(s) and Phone Numbers:

Jon Brumbaugh
Director, Regulatory Affairs
Phone (888) 345-0374; Fax (503) 635-9936

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Jon Brumbaugh
Director, Regulatory Affairs
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Re: K003454
Trade Name: BIOTRONIK A1-CS-SB Y-Adapter
Regulatory Class: III (three)
Product Code: DTD
Dated: December 18, 2000
Received: December 19, 2000

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003454

2. INDICATIONS FOR USE

Lead adapters, including silicone adapter sleeves, when used in conjunction with their accessories, provide a means of securely connecting pace/sense leads with otherwise mechanically incompatible pacemaker devices.

Division of Cardiovascular & Respiratory Devices
510(k) Number K003454